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UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

FRESENIUS KABI USA, LLC, Plaintiff, v. PAR STERILE PRODUCTS, LLC, and PAR PHARMACEUTICAL COMPANIES, INC., Defendants.	Civil Action No.: 2:16-cv-04544 **COMPLAINT AND DEMAND FOR JURY TRIAL**

Plaintiff, FRESENIUS KABI USA, LLC ("Fresenius Kabi" or "Plaintiff"), with its principal place of business located at Three Corporate Drive, Lake Zurich, Illinois 60047, by its attorneys, brings this action for damages and permanent injunctive relief against Defendants, PAR PHARMACEUTICAL COMPANIES, INC. ("Par Pharmaceutical Cos."), and PAR STERILE PRODUCTS, LLC ("Par Sterile"), Par Pharmaceutical Cos.' wholly-owned subsidiary

(Par Pharmaceutical Cos. and Par Sterile collectively referred to as "Par" or "Defendants"). Plaintiff alleges as follows:

NATURE OF THE ACTION

1. This is an action for damages and injunctive relief against Par for violations of Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2, as well as the antitrust law and common law of the state of New Jersey.

2. Par, a pharmaceutical company that develops, manufactures, and markets high barrier-to-entry products, has engaged in exclusionary and predatory conduct to reduce competition and raise prices at the expense of consumers and payors in the relevant market.

3. The relevant market in this case is vasopressin solution for intravenous injection ("Intravenous Vasopressin Injection") approved by the U.S. Food and Drug Administration ("FDA") for sale in the United States.

4. Intravenous Vasopressin Injection[1] is a potentially life-saving antidiuretic drug that is primarily used in the acute critical care setting to restore blood pressure. It is one of the drugs stocked on crash carts, which are located in areas of patient care in case of a life-threatening occurrence.

5. Par is a monopolist in the relevant market. Even though Intravenous Vasopressin Injection has been available for many decades, Par is now the only company with approval from the FDA selling Intravenous Vasopressin Injection in the United States. Accordingly, Par's share of the relevant market is 100%.

[1] Intravenous Vasopressin Injection is sometimes referred to simply as vasopressin. Given that the active pharmaceutical ingredient for Intravenous Vasopressin Injection also is referred to as vasopressin, Fresenius Kabi has used more precise terminology for purposes of the Complaint.

6. Before Par received FDA approval, Intravenous Vasopressin Injection was marketed and sold as an unapproved drug in the United States for many decades by multiple manufacturers.

7. At various points during that time, Fresenius Kabi and other drug manufacturers competed against Par or its predecessor companies in that market. As a result, consumers (*e.g.*, patients, medical providers, and insurers) enjoyed competitive prices for Intravenous Vasopressin Injection.

8. Since Par received FDA approval, however, the price for Intravenous Vasopressin Injection has skyrocketed. In fact, the price of Intravenous Vasopressin Injection has increased by 2600% – from $5.13 per vial to $138.60 per vial. Normal market forces are not to blame for this dizzying spike in price. Instead, Par has illegally taken advantage of its monopoly position to hike the price for Intravenous Vasopressin Injection far beyond what it would be in a competitive market. As PiperJaffray observed in its analyst report dated March 8, 2016, Intravenous Vasopressin Injection is Par's "largest selling product" and "a high-margin one at that given the absence of competition."

9. Fresenius Kabi is prepared and intends to re-enter the Intravenous Vasopressin Injection market. To do so, Fresenius Kabi must submit an Abbreviated New Drug Application ("ANDA") with the FDA. The FDA requires the ANDA applicant to include information about the active pharmaceutical ingredient ("API") used in its proposed product. API is a substance or mixture of substances used in the production of a drug. It is the essential active ingredient in the drug product used to furnish pharmacological activity. The ANDA applicant must demonstrate that its API supplier has filed a Drug Master File ("DMF") with the FDA in advance of the

submission of the ANDA. As a result, access to API suppliers with an active DMF is essential for an ANDA applicant to enter and compete in the market.

10. More than one drug manufacturer can reference the DMF of the same API supplier in its application. It is necessary within the industry for a drug manufacturer to receive a Letter of Authorization from an API supplier permitting the drug manufacturer to reference a DMF in its application to the FDA.

11. The API used in Intravenous Vasopressin Injection is vasopressin, a man-made form of the polypeptide hormone that is normally produced by the pituitary gland ("Vasopressin API"). There are only three suppliers with an active DMF filed with the FDA for the supply of Vasopressin API in the United States: BCN Peptides ("BCN"); Bachem Americas, Inc. ("Bachem"); and PolyPeptide Laboratories Sweden AB ("PolyPeptide Labs").

12. Unless a competitor, such as Fresenius Kabi, can access Vasopressin API from a supplier with an active and viable DMF filed with the FDA, it cannot file an ANDA to enter the market. Thus, Par can delay the onset of competition and squeeze more multi-million dollar years out of its Intravenous Vasopressin Injection by blocking access to Vasopressin API suppliers who have an active DMF with the FDA.

13. Par itself is keenly aware of the critical importance of having access to FDA-approved sources of API. In its 2014 SEC Form 10-K filed on March 12, 2015, Par explains how its own business would be hurt due to the resulting time delays and substantial cost increases associated with an interruption in its supply of API:

> [C]hanges in our raw material suppliers could result in significant delays in production, higher raw material costs and loss of sales and customers, because regulatory authorities must generally approve raw material sources for pharmaceutical products, which may be time consuming. Any significant supply interruption could have a material adverse effect on our business, condition (financial and other), prospects and results of operations. . . .

14. Threatened by the potential entry of competitors into the relevant market, Par has engaged in an extensive anticompetitive scheme to maintain its monopoly power and unlawfully interfere with competitors' efforts to enter or re-enter the relevant market. Specifically, rather than compete on the merits, Par has leveraged its position as the sole FDA-approved manufacturer of Intravenous Vasopressin Injection to prohibit actual or potential competitors, such as Fresenius Kabi, from accessing Vasopressin API, even solely for the purpose of filing an ANDA.

15. In addition to attempting to prevent any ANDA filings at all, Par also successfully delayed any ANDA filings before Par obtained a patent. On June 28, 2016, Par obtained a patent for its Intravenous Vasopressin Injection. As a result, a competitor is now required to identify as part of its ANDA any patents listed in the Orange Book for the Reference Listed Drug and must certify as to each listed patent either: (a) that no patent information has been filed with the FDA; (b) that the claimed patent has expired; (c) the date on which the filed patent will expire; or (d) that the filed patent is invalid, unenforceable, or will not be infringed by the drug for which approval is sought. 21 U.S.C. § 355(j)(2)(A)(vii)(I)-(IV).

16. Par has resorted to these anti-competitive tactics because the entry of competitors will have a pro-competitive and price-lowering influence in the relevant market. Without access to a Vasopressin API supplier who has an active DMF with the FDA, no competitor can file an ANDA and obtain approval for Intravenous Vasopressin Injection, which is required to enter the market and compete. Thus, Par's actions to block access to suppliers of Vasopressin API with an active DMF have been taken with the purpose and intent of monopolizing or maintaining a monopoly in the relevant market by blocking and delaying the entry or re-entry of competitors into the market.

17. As Par *admits* in its own statements to the public and investors, Par's strategy was intended to, and has had the effect of, substantially foreclosing competition, restricting entry, constraining output, maintaining supracompetitive prices, and curtailing consumer choices in the relevant market. When asked about the competitive dynamics of the Intravenous Vasopressin Injection market during a May 5, 2016, call with analysts regarding first quarter earnings, Par's President, Paul Campanelli ("Campanelli"), stressed the importance and success of Par's anticompetitive strategy to lock-up the supply of Vasopressin API. According to Mr. Campanelli:

> Regarding [Intravenous Vasopressin Injection], *right now we are well protected with our API source. From that standpoint we feel as though that we are well-positioned at least through 2017 on the exclusive basis.* We are working very diligently with the PTO in order to get patent status, which you would then have our legal team immediately list the patent to the Orange Book. That has not happened yet, in progress. *But at this point in time, our defense is really our API source; that should get us through at least 2017.* (emphasis added)

18. During the same call, Mr. Campanelli quantified the success of Par's anticompetitive strategy when he corrected an analyst who thought Par's Intravenous Vasopressin Injection sales would break $200 million this year by stating "it's a little bit larger than you had indicated. It's in excess of around $300 million."

19. By leveraging its monopoly power in the Intravenous Vasopressin Injection market, Par is able to extract monopoly profits from the market. Its exclusionary conduct has enabled it to maintain its monopoly position by delaying the onset of competition for Intravenous Vasopressin Injection in the United States. Par's anticompetitive tactics to block Fresenius Kabi and other competitors from re-entering or entering the Intravenous Vasopressin Injection market has caused consumers and payors to pay significantly higher prices to treat the life threating conditions addressed by Intravenous Vasopressin Injection.

THE PARTIES

20. Plaintiff Fresenius Kabi is engaged in the business of developing, manufacturing and marketing generic pharmaceuticals. Fresenius Kabi is a Delaware limited liability company with its principal place of business at Three Corporate Drive, Lake Zurich, Illinois 60047.

21. Defendant Par Sterile is a limited liability company organized under the laws of the state of Delaware. Par Sterile focuses on the U.S. sterile injectable drug market. It manufactures and sells branded and generic aseptic injectable pharmaceuticals in hospital and clinical settings, and provides contract manufacturing services for global pharmaceutical companies. Its principal place of business is located at One Upper Pond Road, Building D, 3rd Floor, Parsippany, New Jersey 07054.

22. Defendant Par Pharmaceutical Cos., incorporated in 1978 as Par Pharmaceutical, Inc., is a Delaware holding company that specializes in developing, licensing, manufacturing, marketing and distributing high-barrier-to-entry products in the United States. It operates in two business segments: (a) Par Pharmaceutical, which includes generic products marketed under Par Pharmaceutical and sterile products marketed under Par Sterile; and (b) Par Specialty Pharmaceuticals, which markets branded products. Par Pharmaceutical Cos.' principal executive offices are located at One Ram Ridge Road, Chestnut Ridge, New York 10977, and it also has a place of business in Woodcliff Lake, New Jersey 07677.

JURISDICTION AND VENUE

23. Fresenius Kabi brings this lawsuit pursuant to Sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15 and 26, to recover damages and the costs of suit, including reasonable attorneys' fees; to enjoin Par's anticompetitive conduct; and for such other relief as is afforded

under the antitrust laws of the United States for Par's violations of Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2, and other state related claims.

24. This Court has federal question jurisdiction over this matter pursuant to 28 U.S.C. § 1331 in that the causes of action asserted in this complaint arise under the laws of the United States. This Court has supplemental jurisdiction over the causes of action asserted under state law pursuant to 28 U.S.C. § 1367 because the state law causes of action are so related to the causes of action within the Court's federal question jurisdiction that the state law causes of action form part of the same case or controversy.

25. Venue is proper in this district pursuant to 28 U.S.C. § 1391 (b)-(d) because a substantial part of the events giving rise to Plaintiff's claims occurred in this District, a substantial portion of the affected interstate trade and commerce described below has been carried out in this District, and one or more Defendants reside, are licensed to do business in, are doing business in, have and had agents in, and are found to transact business in this District.

RELEVANT MARKET

A. Relevant Product Market

26. The relevant product market in this case is Intravenous Vasopressin Injection approved by the FDA for sale in the United States.

27. Intravenous Vasopressin Injection is a drug indicated in emergency situations to increase blood pressure in patients with vasodilatory shock (*e.g.*, post-cardiotomy or sepsis) who continue to have low blood pressure after receiving fluids and medicines.

28. Septic shock is a form of distributive shock that occurs in patients with sepsis and comprises of an underlying circulatory and cellular/metabolic abnormality that is associated with increased mortality. The hallmark of septic shock is marked peripheral arteriolar vasodilation,

which results in low systemic vascular resistance, high cardiac output, severe hypotension, and inadequate tissue perfusion.

29. Therapy for vasodilatory shock typically includes the administration of Intravenous Vasopressin Injection in conjunction with a drug category known as catecholamines, which include drugs such as norepinephrine.

30. Intravenous Vasopressin Injection is capable of causing vasoconstriction and water retention. Intravenous Vasopressin Injection mediates vasoconstriction via V_1-receptor activation on vascular smooth muscle. Both the narrowing of the blood vessels and the increase in blood volume due to water retention cause an increase in blood pressure.

31. The infusion of Intravenous Vasopressin Injection also improves responsiveness to infused catecholamines and allows patients to be weaned off of catecholamines. Reduction in catecholamine requirements may mitigate adverse effects on immune function, coagulation, metabolic efficiency, and stimulation of bacterial growth.

32. There are no reasonable substitutes for Intravenous Vasopressin Injection. The ability to increase Intravenous Vasopressin Injection prices above their competitive levels is not reasonably constrained by the price of other products. Consequently, a monopolist of Intravenous Vasopressin Injection (*i.e.,* Par) has and will continue to profitably maintain supracompetitive prices for Intravenous Vasopressin Injection over a sustained period of time.

B. Relevant Geographic Market

33. The relevant geographic market in which to assess the anticompetitive effects of Par's conduct is the United States. The FDA's elaborate regulatory process for approving drugs for sale in the United States, and the fact that the marketing, sales, and distribution of pharmaceuticals occur on a nationwide basis, establish the boundaries of the geographic market.

C. Barriers to Entry

34. There are significant barriers to entry in the relevant market.

35. The development, manufacturing, sales, marketing and distribution of pharmaceutical products are subject to extensive statutory and regulatory oversight by the U.S. federal government, primarily by the FDA.

36. A drug cannot be manufactured for sale in the United States without FDA approval. There are substantial costs, expertise, and lead times required to formulate, develop, and obtain federal approval for the manufacture and distribution of generic pharmaceuticals. To obtain FDA approval of a version of an already approved drug, a drug manufacturer must file an ANDA to establish that its version of the drug is therapeutically equivalent to the FDA-approved drug. FDA approval takes an average of 24 to 30 months, although the approval process can take up to three years or more. Injectable drugs are generally more complex than other forms of drugs and can often be subject to a longer and more complex approval process.

37. Par admits in its public filings that it deliberately targets "high barrier-to-entry products" that have limited competition and long life cycles.[2] Moreover, Par has acknowledged the existence and impact of the high-entry barriers specifically associated with sterile injectables, such as Intravenous Vasopressin Injection. During a May 16, 2014, call with analysts, Mr. Campanelli admitted:

> Par Sterile products represents a transformational acquisition for us. Beyond just running our product portfolio, the acquisition positions Par in a growing market with higher barriers to entry. Injectables are capital intensive and technically challenging with demanding quality and compliance requirements. These barriers to entry typically result in few of the generic entrants in specific product categories and longer product life cycles.

[2] *See, e.g.,* Par Pharmaceuticals Inc., *Annual 10-K Report*, *available at* https://www.sec.gov/Archives/edgar/data/878088/000087808815000002/prx-20141231x10k.htm

38. Par's parent company, Endo International PLC ("Endo"), also has acknowledged the importance of the high-entry barriers associated with sterile injectables. During a February 29, 2015, call with analysts regarding fourth quarter earnings, Endo's President and CEO, Rajiv De Silva, stated:

> [S]terile injectables have tripled in net sales since Par acquired JHP in 2014 and those products have high barriers to entry, high margins and strong competitive positioning and growth potential. We project significant continued double-digit growth with gross margins well above the Company average for this segment in 2016. . . .

D. Interstate Commerce

39. Par manufactured and sold Intravenous Vasopressin Injection in the United States in a continuous and uninterrupted flow of interstate commerce, including through and into this judicial district.

40. Par's business activities were intended to and did have a substantial effect on the interstate commerce in the United States, including this judicial district.

41. In its March 8, 2016, analyst report, PiperJaffray noted that Par had total sales of $359 million for its fourth quarter of 2015. PiperJaffray estimated that Par's Intravenous Vasopressin Injection accounted for 12%-15% of those quarterly sales.

ADDITIONAL FACTUAL BACKGROUND

A. Multiple Competitors Participated In The Intravenous Vasopressin Injection Market Before FDA Approval Was Required

42. The original Federal Food and Drugs Act of 1906 brought drug regulation under federal law. That Act prohibited the sale of adulterated or misbranded drugs, but did not require that drugs be approved by FDA. In 1938, Congress passed the Food, Drug and Cosmetic Act ("FDCA"), which required all "new drugs" to be approved for safety. In 1962, Congress amended the 1938 law to require manufacturers to show that their drug products were effective,

as well as safe. As a result, all drugs approved between 1938 and 1962 had to be reviewed again for effectiveness. For historical reasons, some drugs have been marketed in the United States without FDA approval. Typically, such unapproved drugs were on the market prior to the relevant enactment date of and amendments to the FDCA.

43. Vasopressin has been marketed as a therapeutic agent since before 1938. As a result, Intravenous Vasopressin Injection was marketed and sold as an unapproved drug in the United States until Par received FDA approval in April 2014.

44. During this period, several manufacturers competed in the Intravenous Vasopressin Injection market. Fresenius Kabi (or one of its predecessor companies) sold an Intravenous Vasopressin Injection at least as early as October 1999, and continued to do so until March 15, 2015.

45. JHP Pharmaceuticals, LLC also sold an Intravenous Vasopressin Injection under the name Pitressin. Par subsequently acquired JHP Pharmaceuticals, LLC for $490 million, and renamed the company Par Sterile. As part of the acquisition, Par assumed ownership and control over Pitressin.

46. In recent years, the FDA has encouraged drug manufacturers to seek FDA approval for marketed unapproved products. On September 19, 2011, the FDA published a document styled "*Marketed Unapproved Drugs – Compliance Policy Guide*." In its document, the FDA re-issued guidance to drug manufacturers by stating that it would take steps to "encourage the manufacturers of these products to obtain the required evidence and comply with

the approval provisions of the Federal Food, Drug, and Cosmetic Act [] or remove the products from the market."[3]

47. On September 26, 2012, Par submitted to the FDA a New Drug Application ("NDA") (NDA No. 204485) for its Intravenous Vasopressin Injection under the name Vasostrict, pursuant to Section 505(b)(2) of the FDCA, 21 U.S.C. § 355(b)(2).

B. Par Becomes The Sole FDA-Approved Manufacturer Of Intravenous Vasopressin Injection

48. On April 17, 2014, the FDA issued an NDA Approval Letter that authorized Par to market and sell Vasostrict to increase blood pressure in adults with vasodilatory shock (e.g., post-cardiotomy or sepsis) who remain hypotensive despite fluids and catecholamines. Par, however, waited until November 2014 to launch Vasostrict. During the time between April and November 2014, Par continued to sell Pitressin. Fresenius Kabi also continued to market and sell its Intravenous Vasopressin Injection.

49. Although the FDA has an interest in encouraging manufacturers of unapproved drugs to comply with the approval provisions of the FDCA, its guidelines note that the FDA "want[s] to achieve these goals without adversely affecting public health, imposing undue burdens on consumers, or unnecessarily disrupting the market." As a result, the FDA exercises discretion to determine whether, when and how it will pull unapproved drugs from the market. Its guidelines state that the "FDA intends to evaluate on a case-by-case basis whether justification exists to exercise enforcement discretion. . . ." If the FDA decides to take enforcement action, it typically allows for a grace period of a year or more before removing an

[3] U.S. Department of Health and Human Services Food and Drug Administration, *Guidance for FDA Staff and Industry: Marketed Unapproved Drugs – Compliance Policy Guide*, (September 19, 2011) *available at* http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm070290.pdf.

unapproved drug from the market to mitigate the undue burdens on consumers or the possibility of unnecessarily disrupting the market.

50. Par was concerned about the impact such a grace period would have on its monopoly profits and therefore launched a campaign to force Fresenius Kabi out of the Intravenous Vasopressin Injection market. First, on May 7, 2014, less than one month after receiving FDA approval for Vasostrict, Par filed a federal complaint under the Lanham Act based on how Fresenius Kabi was describing its Intravenous Vasopressin Injection to the market. That lawsuit was ultimately dismissed without prejudice.

51. Second, upon information and belief, after receiving FDA approval for Vasostrict, Par contacted the FDA on multiple occasions regarding Fresenius Kabi's sale of its Intravenous Vasopressin Injection. Upon information and belief, Par wanted the FDA to remove Fresenius Kabi's Intravenous Vasopressin Injection from the market so that Par could monopolize the market with Pitressin until Par was prepared to launch Vasostrict.

52. On November 14, 2014, Par issued a press release announcing that it received FDA approval for Vasostrict. In the release, Par states "Vasostrict is the first and only vasopressin injection, USP, product with an NDA approved by the FDA. Vasostrict is indicated to increase blood pressure in adults with vasodilatory shock (e.g., post-cardiotomy or sepsis) who remain hypotensive despite fluids and catecholamines." At this time, Par began selling Vasostrict on the market.

53. On December 15, 2014, the FDA instructed Fresenius Kabi to cease manufacturing its Intravenous Vasopressin Injection product by January 30, 2015, and to cease distribution by March 15, 2015.

54. Fresenius Kabi always intended to market an FDA-approved Intravenous Vasopressin Injection. As early as 2008, Fresenius Kabi was engaged in its own development program to file an NDA to obtain FDA-approval for Intravenous Vasopressin Injection. Once the FDA approved Par's NDA, Fresenius Kabi adjusted its development program to focus on filing an ANDA. Before and after it discontinued distribution of its Intravenous Vasopressin Injection on March 15, 2015, Fresenius Kabi continued with its development program to obtain FDA approval for its Intravenous Vasopressin Injection.

55. Since Par has become the sole FDA-approved supplier of Intravenous Vasopressin Injection, the price of Intravenous Vasopressin Injection has drastically increased. In November 2014, after Par received FDA approval for Vasostrict and pulled Pitressin from the market (but still faced competition from Fresenius Kabi), the Average Wholesale Price ("AWP") of Intravenous Vasopressin Injection was $5.13 per vial. In April 2016, when Par faced no competition, the AWP of Intravenous Vasopressin Injection increased to $138.60 per vial. As a result, the price for Intravenous Vasopressin Injection has increased by 2600% since Par received FDA approval.

56. Par's profit margins also have soared since it became the sole FDA-approved supplier of Intravenous Vasopressin Injection. According to a PiperJaffray analyst report dated March 8, 2016, Vasostrict is Par's "largest selling product" and a "key driver" in its generic segment. The same report described Vasostrict as a "high-margin generic without any competition" that is annualizing approximately $175 to $200 million in sales. The report further asserts that it is "safe to assume that gross margins are essentially brand-like" because Vasostrict "is the only vasopressin product on the market."

57. Entry of a second manufacturer of Intravenous Vasopressin Injection into the market would necessarily erode Par's sales of Vasostrict and Par's profits. Accordingly, Par desires to maintain its position as the sole FDA-approved manufacturer of Intravenous Vasopressin Injection in the United States.

C. Fresenius Kabi Is Prepared And Intends To Re-Enter The Market For Intravenous Vasopressin Injection

58. Fresenius Kabi is prepared and intends to re-enter the U.S. market for Intravenous Vasopressin Injection. Soon after Par obtained FDA approval for Vasostrict, Fresenius Kabi converted its NDA development program to focus on filing an ANDA with the FDA to obtain approval to sell Intravenous Vasopressin Injection in the United States.

59. Once the first manufacturer of a particular drug files an NDA, any subsequent manufacturer of the same drug may file an ANDA to obtain approval for its version of the drug. The subsequent filer must establish through the ANDA that its version of the drug is pharmaceutically and therapeutically equivalent to the FDA-approved drug, known as a reference listed drug ("RLD").

60. FDA approval of an ANDA takes an average of 24 to 30 months, although the approval process can take up to three years or more. Once approved, an ANDA applicant may manufacture and market the generic drug product to provide a safe, effective, low-cost alternative to consumers.

61. To receive regulatory approval, the FDA requires the ANDA applicant to include information about the manufacture and testing of the API used in its proposed product. Typically the ANDA applicant purchases the API from a specialty chemical manufacturer ("API Supplier"), and then combines the API with solubilizers, stabilizers, and other excipients to produce the finished product.

62. The ANDA applicant must identify an API Supplier that has an active DMF with the FDA in its ANDA. The DMF explains the processes that the API Supplier uses to make the API and the specifications for testing and release of the API.

63. The FDA discloses only certain portions of a DMF because it contains confidential information relating to an API Supplier's manufacturing methods and processes. The portion of the DMF available to the public is called the "open part," and the portion not available to the public is called the "closed part."

64. The ANDA applicant may incorporate by reference the API Supplier's active DMF so long as the API Supplier authorizes such a reference. The reference is typically called a Letter of Authorization ("LOA"), which is sent by the API Supplier to the FDA with a copy to the ANDA applicant. More than one drug manufacturer can reference the DMF of the same API Supplier in its application.

65. For these reasons, access to API Suppliers with active DMFs filed with the FDA and with active track records in FDA-approved products is critical to competition in the relevant market. Par admits as much when it stated in its own 2014 SEC Form 10-K filed on March 12, 2015, that a substantial risk to the development and commercialization of a new product is "the availability, on commercially reasonable terms, of raw materials, including APIs and other key ingredients. . . ." The inability of a new drug applicant to access API Suppliers with an active and viable DMF filed with the FDA prevents it from filing an ANDA to enter the market.

66. As previously alleged, the API used in Intravenous Vasopressin Injection is Vasopressin API. Vasopressin API is a white to off-white amorphous powder, freely soluble in water.

67. Three suppliers have an active DMF filed with the FDA for the supply of Vasopressin API in the United States: BCN; Bachem; and PolyPeptide Labs. BCN previously supplied Vasopressin API for Fresenius Kabi's Intravenous Vasopressin Injection. Bachem also previously supplied Vasopressin API samples to Fresenius Kabi for testing. None of these suppliers, however, are available to support Fresenius Kabi's ANDA.

68. As set forth below, Par has entered into an anticompetitive exclusive dealing agreement with BCN. This arrangement alone has substantially foreclosed the market for Intravenous Vasopressin Injection because it prevents competitors from obtaining the necessary input to enter the market. The two remaining suppliers with an active DMF to manufacture Vasopressin API, Bachem and PolyPeptide Labs, are also subject to unduly restrictive exclusive dealing arrangements. Upon information and belief, Par has entered into a restrictive exclusive dealing agreement with Bachem.

69. Such agreements have substantially foreclosed Fresenius Kabi's ability to purchase Vasopressin API and to compete with Par. As noted in PiperJaffray's March 8, 2016 analyst report styled "*A Closer Look At Vasostrict; Competition Not A Nearer-Term Threat*," "competition is most likely a couple of years away (and could be very limited)." PiperJaffray attributes the lack of a competitive threat to the "*potential active pharmaceutical ingredient (API) scarcity*." (emphasis added.) According to PiperJaffray:

> The paucity of active DMFs (only one related to API) reinforces our view that competition this year or even next is unlikely (and may be limited if it did come to pass). Put another way, it is hard for us to see longer-term Vasostrict competition pressuring the top-line particularly in the context of a deep aNDA [sic] that will eventually bear fruit.

70. With the requisite supply of Vasopressin API from BCN, Fresenius Kabi would have been prepared to file its ANDA in the Spring/Summer 2016 with an anticipated launch set

for 2018. Fresenius Kabi's entry into the market will have the effect of lowering the price of Intravenous Vasopressin Injection.

PAR'S MARKET POWER

71. Par has market power in the relevant market.

72. Currently, Par is the only company with FDA approval to sell Intravenous Vasopressin Injection for use in the United States. Accordingly, Par's share of the relevant market is 100%.

73. Another indication of Par's market power is its ability to raise and maintain the price of Intravenous Vasopressin Injection at supracompetitive levels without losing substantial sales. Since receiving FDA approval, Par has increased the price for Intravenous Vasopressin Injection by 2600%.

PAR'S ANTICOMPETITIVE CONDUCT

A. Par Has Willfully Maintained Its Substantial Market Power Through The Use Of Anticompetitive Exclusionary Conduct

74. Par has not maintained its monopoly power through meritorious competition. Rather it has done so through unlawful, exclusionary conduct in violation of federal and state antitrust laws.

75. After obtaining FDA approval for Vasostrict in April 2014, Par has embarked on a strategy to maintain its monopoly with anticompetitive exclusive dealing, which prevents competitors from obtaining Vasopressin API to file an ANDA and eventually manufacture Intravenous Vasopressin Injection.

76. BCN, Bachem, and PolyPeptide Labs are the only suppliers with an active DMF filed with the FDA to manufacture Vasopressin API in the United States. Fresenius Kabi has approached all three of these companies and none are available.

77. Par has entered into an anticompetitive exclusive dealing agreement with BCN, which previously supplied Vasopressin API for Fresenius Kabi's Intravenous Vasopressin Injection. Bachem and PolyPeptide Labs are also locked into exclusive contracts for Vasopressin API. Upon information and belief, Par has entered into an unduly restrictive exclusive dealing agreement with Bachem.

1. BCN

78. BCN is a privately owned company based in Barcelona, Spain, which is in the business of, among other things, manufacturing bioactive peptides for pharmaceutical applications.

79. BCN is one of three suppliers of Vasopressin API with an active DMF. In the past, BCN supplied Vasopressin API to both Fresenius Kabi and Par.

80. The relationship between Fresenius Kabi and BCN began in early 2011. On or about February 2011, Fresenius Kabi contacted BCN about receiving Vasopressin API. At that time, Fresenius Kabi's primary supplier, NV Organon, announced that it was discontinuing its production of Vasopressin API. During a telephone call between Tom Jacobson of Fresenius Kabi and Dr. Jordi Piro of BCN, Dr. Piro indicated that BCN was interested in becoming Fresenius Kabi's alternative supplier of Vasopressin API. On or about July 20, 2012, Fresenius Kabi began selling Intravenous Vasopressin Injection with BCN as its new supplier of Vasopressin API.

81. As early as 2008, Fresenius Kabi was engaged in its own development program to file an NDA to obtain FDA-approval for Intravenous Vasopressin Injection. Soon after Par obtained FDA approval for Vasostrict, Fresenius Kabi altered its own development program to

file an ANDA with the FDA to obtain approval to sell Intravenous Vasopressin Injection in the United States. At the time, BCN pledged to help Fresenius Kabi with its ANDA.

82. On or about January 15, 2015, Mr. Jacobsen of Fresenius Kabi sent an e-mail to Dr. Piro of BCN. In his e-mail, Mr. Jacobsen updated Dr. Piro that Fresenius Kabi was continuing with its work in regard to its ANDA filing to the FDA for Intravenous Vasopressin Injection. In response, Dr. Piro expressed his enthusiasm about Fresenius Kabi's intent to move forward with its ANDA filing.

83. On or about February 2015, Georg Eckel of Fresenius Kabi and Dr. Piro of BCN spoke on the telephone regarding BCN's Vasopressin API. During the telephone call, Dr. Piro confirmed that BCN was supporting the reference listed drug ("RLD"), which meant that BCN was the Vasopressin API supplier for Par's NDA related to Vasostrict.

84. On or about April 13, 2015, Mr. Jacobsen of Fresenius Kabi informed Dr. Piro of BCN that Fresenius Kabi was proceeding with its development project to submit its ANDA for Intravenous Vasopressin Injection and requested batches of Vasopressin API for testing. In response, Dr. Piro explained that BCN had Vasopressin API in stock and that it would provide that material to Fresenius Kabi for its testing.

85. On or about May 26, 2015, Mr. Jacobsen and Haris Jamil of Fresenius Kabi spoke with Dr. Piro of BCN regarding BCN's Vasopressin API. The purpose of the conversation was to resolve questions and request materials in furtherance of Fresenius Kabi's ANDA. Mr. Jacobsen and Mr. Jamil requested, among other things, BCN's Vasopressin Assay method with Validation Report and Vasopressin Impurity method with Validation Report. Dr. Piro provided the requested materials at a later date.

86. On July 1, 2015, Fresenius Kabi sent a letter notifying the FDA that BCN would import 100 grams of Vasopressin API on its behalf. In its letter, Fresenius Kabi explained:

> FK USA will use this bulk active pharmaceutical ingredient (API) for the research and development of Vasopressin for Injection only. FK USA is currently preparing a submission for the Food and Drug Administration (FDA) for Vasopressin Injection. . . . FK USA affirms that 100 g of Vasopressin is a reasonable quantity for research and development purposes. . . .

87. In July 2015, Fresenius Kabi also sent BCN a Request for Quotation ("RFQ"), which requested that BCN provide a LOA regarding Vasopressin API in support of Fresenius Kabi's ANDA to the FDA. It was customary for Fresenius Kabi to submit an RFQ for BCN's Vasopressin API on an annual basis. The purpose was to provide an estimated forecast of Fresenius Kabi's needs for the upcoming year.

88. On July 23, 2015, the CEO of BCN, Berta Ponsati, called Dr. Michael Schoenhofen, Ph.D. of Fresenius Kabi to request a face-to-face meeting. Dr. Schoenhofen met with Ms. Ponsati and Dr. Piro at a restaurant located in the Steigenberger Airport Hotel in Frankfurt, Germany. During the meeting, Ms. Ponsati stated that BCN received an extremely rich offer for its Vasopressin API and, as a result, BCN would not be able to supply Vasopressin API to Fresenius Kabi. She then proposed that BCN and Fresenius Kabi consider other projects where BCN could provide different types of API. In response, Dr. Schoenhofen proposed that BCN at least support Fresenius Kabi's ANDA for its Intravenous Vasopressin Injection. Ms. Ponsati expressed interest in the proposal and promised to respond after consulting with her business partner.

89. In September 2015, Ms. Ponsati informed Dr. Schoenhofen that BCN was unable to supply Fresenius Kabi with Vasopressin API because of Par's exclusivity arrangement. Ms.

Ponsati further indicated that Par would not permit BCN to provide support for Fresenius Kabi's ANDA.

90. In light of the past business relationship between Fresenius Kabi and BCN regarding Vasopressin API and BCN's initial support for Fresenius Kabi's ANDA, Fresenius Kabi attempted to obtain at least an LOA from BCN in support of Fresenius Kabi's ANDA following the September 2015 discussion between Ms. Ponsati and Dr. Schoenhofen.

91. On October 12, 2015, Mr. Jacobsen of Fresenius Kabi visited BCN's exhibit booth at the CPHI Conference. Mr. Jacobsen spoke with Dr. Piro of BCN about Fresenius Kabi's RFQ for Vasopressin that was sent to BCN in July. In the past, BCN promptly responded to all of Fresenius Kabi's RFQs. Thus, Mr. Jacobsen asked when Fresenius Kabi would receive BCN's response to the outstanding RFQ. Dr. Piro informed Mr. Jacobsen that BCN was reviewing the RFQ and planned to respond to Fresenius Kabi within the next week.

92. Fresenius Kabi continued to prepare its ANDA between October and November 2015. During that period, Fresenius Kabi's Research and Development group and its Regulatory Department submitted technical and regulatory questions regarding BCN's Vasopressin API to Mr. Jacobsen, who then forwarded those questions to Dr. Piro. Mr. Jacobsen did not receive a response to those questions from Dr. Piro or any other BCN representative.

93. On December 11, 2015, Fresenius Kabi representatives met with representatives from BCN and its sister company GP Pharm in Barcelona, Spain, to discuss, among other things, whether BCN would supply Vasopressin API to Fresenius Kabi or, at the very least, provide an LOA in support of Fresenius Kabi's ANDA for Intravenous Vasopressin Injection. Specifically, Marc-Alexander Mahl, Martin Hofmann and Georg Eckel, all of Fresenius Kabi, met with Ms. Ponsati and Dr. Piro of BCN, and Alex La Fuente and Rob Hoen of GP Pharm.

94. During the meeting, the BCN representatives stated that BCN was unable to supply Fresenius Kabi because BCN was bound by an exclusive contract imposed by Par that prohibited BCN from supplying Vasopressin API to Fresenius Kabi or any other manufacturer. The BCN representatives explained that the exclusive contract provided BCN with a significant payment upon execution and additional future payments for every year that BCN did not support any other market entrant for Intravenous Vasopressin Injection. Upon information and belief, the total value of the contract is more than ten million dollars.

95. The amount of Vasopressin API required to support the entire U.S. market for Intravenous Vasopressin Injection is worth hundreds of thousands of dollars, not millions of dollars. Upon information and belief, Par overpaid for BCN's Vasopressin API to avoid having to compete with potential entrants.

96. During the same December 11 meeting, the Fresenius Kabi representatives then asked whether BCN would continue to support Fresenius Kabi's ANDA by providing an LOA. In response, the BCN representatives stated that they raised the issue with Par and Par said no. The BCN representatives further stated that the agreement with Par prohibits BCN from supporting any other entrant, and that BCN could release LOAs to customers only after another generic using a different Vasopressin API supplier entered and operated in the market.

97. Although BCN could not supply Fresenius Kabi in the U.S. market, the BCN representatives confirmed that BCN could supply Fresenius Kabi with Vasopressin API for the Intravenous Vasopressin Injection markets outside of the United States.

98. The exclusive agreement was not reasonably necessary to protect Par's supply of Vasopressin API. Because BCN would have been free to supply the same Vasopressin API for use in Intravenous Vasopressin Injections sold outside of the United States, any Par restriction

prohibiting BCN from supplying Vasopressin API to Fresenius Kabi cannot be justified on the purported basis that an exclusive agreement was necessary to ensure a reliable supply of Vasopressin API.

99. By preventing Fresenius Kabi from obtaining an LOA, Par successfully insulated itself from the prospect of future competition by forestalling Fresenius Kabi's ability to even start the regulatory approval process.

2. Bachem

100. Bachem is an independent, technology-based, public biochemical company, headquartered in Bubendorf, Switzerland, which provides full service to the pharmaceutical and biotech industry.

101. Bachem previously provided Fresenius Kabi with samples of Vasopressin API.

102. On November 24, 2015, Mr. Jacobsen of Fresenius Kabi spoke by telephone with DeAnna Long of Bachem. The purpose of the call was to determine whether Bachem was interested in supplying Vasopressin API to Fresenius Kabi. During the call, Ms. Long confirmed that Bachem has an active DMF, but stated it has an exclusive agreement with someone else. In addition, shortly after the call, Ms. Long sent an e-mail stating "we cannot offer vasopressin."

103. At the end of 2015, Nina Ullrich of Fresenius Kabi received a telephone call from Andre Casadrdne of Bachem. Although Mr. Casadrdne called to discuss other products, Ms. Ullrich asked whether Bachem would support Fresenius Kabi's ANDA for Intravenous Vasopressin Injection. In response, Mr. Casadrdne stated that he thought Bachem already had an exclusive contract with another customer, but he would check with his colleague at Bachem U.S. because that is where the contracts were located.

104. On March 16 and 17, 2016, Fresenius Kabi representatives met with representatives from Bachem at the DCAT International Fair. Specifically, Mr. Eckel, Ms. Ullrich and Peter Mirold, all of Fresenius Kabi, met with Mr. Casadrnde, Kathrin Stoller and Alein Sondenecker, all of Bachem. During one of the meetings, the Fresenius Kabi representatives raised the subject of Vasopressin API. In response, Ms. Stoller stated that Bachem had an exclusive contract with another customer that covered the global market. She further stated that the contract was based on the current market situation, which meant that the earliest Bachem could discuss Vasopressin API would be at the end of 2017. If market conditions did not change, however, then the customer had the right to extend the term of the contract.

105. On April 7, 2016, Fresenius Kabi representatives met with representatives from Bachem in Fresenius Kabi's office in Sweden to discuss, among other things, Vasopressin API. Specifically, Mr. Eckel and Ms. Ullrich, all of Fresenius Kabi, met with Mr. Casadrnde, Ms. Stoller and Ms. Sondenecker, all of Bachem. During the meeting, the Bachem representatives stated that it had a worldwide exclusive contract with a customer, which contained a provision that allowed the customer to extend the agreement for a period of time if sales remained the same. The Bachem representatives further stated that the exclusive contract prohibited Bachem from shipping Vasopressin API to any other customer.

106. Because the Bachem representatives stated the exclusive contract for the supply of Vasopressin API will be extended if sales remain the same and because Par is the only entity selling Intravenous Vasopressin Injection, upon information and belief, the exclusive agreement for Bachem's Vasopressin API is likely with Par.

3. PolyPeptide Labs

107. PolyPeptide Labs, the third supplier that has an active DMF for Vasopressin API, is a contract manufacturing organization for peptides and peptide related molecules.

108. On December 2, 2015, Ms. Ullrich of Fresenius Kabi contacted Claudia Lindwall and Sebastian Stenderup of PolyPeptide Labs to ask whether PolyPeptide Labs would support Fresenius Kabi's ANDA for Intravenous Vasopressin Injection. PolyPeptide Labs responded that it could not support Fresenius Kabi in the United States because of an exclusive contract.

109. In March 2016, Mr. Eckel of Fresenius Kabi contacted PolyPeptide Labs about the possibility of obtaining Vasopressin API. PolyPeptide Labs responded that it could not supply Vasopressin API to Fresenius Kabi in the United States because of an exclusive contract with another customer.

B. Par's Exclusionary Conduct Results In Substantial Foreclosure Of The Relevant Market

110. Upon information and belief, Vasostrict accounts for a bulk of Par's profit margin. Par leverages its monopoly power in the Intravenous Vasopressin Injection market to extract monopoly profits. Par accomplished this goal by: (a) restraining competition from new entrants; and (b) maintaining supracompetitive prices for Intravenous Vasopressin Injection for extended periods of time.

111. After acquiring FDA approval in April 2014, Par aggressively embarked on a plan to prevent the entry of competitors into the market for Intravenous Vasopressin Injection. Specifically, Par has used anticompetitive exclusive dealing to lock up difficult-to-source API. Upon information and belief, Par overpaid for API to avoid having to compete with potential entrants. Upon information and belief, Par also engaged in this anticompetitive conduct to prevent an ANDA from being filed before it received a patent. By preventing the filing of an

ANDA before receiving a patent, which Par obtained on June 28, 2016, Par has achieved an additional 30 months of delayed generic entry pursuant to the Hatch-Waxman Act. The purpose of the strategy is to intimidate market entrants and to raise rivals' costs in an effort to prevent their entry or re-entry into the market.

112. Par admits in its own statements to the public and investors that it is creating additional hurdles to delay competitors from entering the relevant market. During an investor call on February 29, 2016 regarding fourth quarter earnings, Mr. Campanelli stated:

> So Vasostrict, remember is an NDA, right? So that was filed as a 505(b)(2), so it's not a generic product. Our goal will be to have proper and appropriate protection on a go-forward basis. That's something that we're working very, very hard and close with the patent trade office. Again but, at this point there's certain things that are unknown. But again, we are looking to protect that product as you would expect from an NDA standpoint.

113. In a more recent call with analysts in May 2016, Mr. Campanelli admitted that locking-up the supply of Vasopressin API was one of the hurdles created by Par to delay competition:

> Regarding [Intravenous Vasopressin Injection], right now we are well protected with our API source. From that standpoint we feel as though that we are well-positioned at least through 2017 on the exclusive basis. We are working very diligently with the PTO in order to get patent status, which you would then have our legal team immediately list the patent to the Orange Book. That has not happened yet, in progress. But at this point in time, our defense is really our API source; that should get us through at least 2017.

114. Such statements have resonated with investors. On March 8, 2016, PiperJaffray wrote with regard to Vasostrict: "[t]he paucity of active DMFs . . . reinforces our view that competition this year or even next is unlikely (and may be limited if it did come to pass)." In the same analyst report, PiperJaffray also wrote:

> Lastly, we would keep in mind that ENDP/Par (sic) does have patent applications pending before the U.S. Patent and Trademark Office (USPTO), so the potential listing of a patent in the Orange Book could turn an aNDA (sic) into a litigated,

> paragraph IV process. . . . Given this backdrop, we would be surprised to see competitors anytime soon. In our view, an entrant two to three years from now seems like a more realistic possibility.

115. By itself, the exclusive contract that Par maintains with BCN provides Par the ability to control a significant supply of Vasopressin API in the United States market.

116. Per the terms of the agreement, BCN is prohibited from supplying Fresenius Kabi the requisite Vasopressin API in the United States. Because BCN is free to supply Fresenius Kabi in other markets outside the United States, the contract cannot be justified on the basis that it ensures a reliable supply. Instead, the contract is intended to cut off competitors' access to difficult-to-source API that is necessary to compete with Par on a level playing field. This agreement itself provides direct evidence that Par has exercised its monopoly power by excluding competitors from resources needed to compete with Par.

117. Par's exclusive control over BCN's supply of Vasopressin API denies competitors, particularly Fresenius Kabi, access to Vasopressin API. Upon information and belief, Par targeted BCN because BCN previously supplied Vasopressin API for Fresenius Kabi's Intravenous Vasopressin Injection. By locking up BCN's Vasopressin API and prohibiting BCN from even providing an LOA to Fresenius Kabi, Par forced Fresenius Kabi to incur significant delays in production, higher raw material costs, and loss of sales and customers.

118. The other potential suppliers of Vasopressin API also are locked up in exclusive contracts.

119. Because of FDA regulations that require a manufacturer to have a sponsor and supplier of its API in its ANDA, Fresenius Kabi is unable to complete its ANDA.

120. As a result, Fresenius Kabi is wholly foreclosed from entering the relevant market.

C. Par's Exclusionary Conduct Has Caused Substantial Anti-Competitive Effects

121. The exclusionary acts and practices of Par as alleged herein have foreclosed Fresenius Kabi and other competitors from entering the relevant market, have restrained trade, and have preserved and entrenched Par's monopoly power. As a result, competition in the relevant market has been damaged and Fresenius Kabi has been injured. Those injuries are intertwined and inseparable. Excluding or delaying Fresenius Kabi from entering the relevant market was and is an integral aspect of Par's anticompetitive conduct.

1. Par's exclusionary conduct has caused consumers and payors to pay supracompetitive prices for Intravenous Vasopressin Injection and has reduced consumer choice.

122. Par's conduct prevents competitors from entering the relevant market, thereby leading to higher prices and reduced consumer choice. As alleged above, Par's exclusionary conduct restricts access to the supply of Vasopressin API, denying any subsequent pharmaceutical manufacturer the ability to complete the FDA-required ANDA and therefore blocks entry into the market.

123. By restricting the entry of competitors, Par's exclusionary conduct deprives consumers and payors the benefits of competition among generic pharmaceutical manufacturers, including lower prices and increased consumer choice.

124. Par's exclusionary conduct has allowed it to maintain its monopoly over the market for Intravenous Vasopressin Injection, and increase the price for Intravenous Vasopressin Injection by 2600% without consequence. As a result of these substantial and unprecedented increases for Intravenous Vasopressin Injection, many purchasers, including pharmacies, hospitals, insurers, managed care organizations, wholesalers, government agencies and others, have paid substantially higher prices.

125. In 2013, when multiple competitors participated in the market, Par's (via its predecessor company) total sales from Intravenous Vasopressin Injection amounted to approximately $4 million. After Par became the sole supplier of Intravenous Vasopressin Injection, its total sales of Intravenous Vasopressin Injection exceeded $50 million in the fourth quarter of 2015 alone. Now, Par projects that its total sales of Intravenous Vasopressin Injection will exceed $300 million in 2016. This explosion in sales figures is the result of Par's ability to raise the price for Intravenous Vasopressin Injection by 2600%.

126. Moreover, because Intravenous Vasopressin Injection is administered in emergency, and often life threatening, situations, many patients do not have a choice in whether Intravenous Vasopressin Injection is administered, and therefore they or their insurers bear the cost regardless of the exorbitant price.

127. As a result of these substantial and unprecedented price increases for Intravenous Vasopressin Injection, Par has profited, and continues to profit, from its unlawful, exclusionary conduct, to the detriment of consumers and payors. According to one analyst report, Vasostrict is one of Par's largest selling drugs and "a high-margin one at that given the absence of competition."

2. Par's exclusionary conduct has injured Fresenius Kabi.

128. Par's anticompetitive conduct has foreclosed Fresenius Kabi from entering the relevant market. As a result, Fresenius Kabi has suffered and continues to suffer injury from Par's preservation of its monopoly.

129. Fresenius Kabi is a potential entrant into the relevant market and, but for Par's unlawful conduct, would be re-entering the relevant market with its own FDA-approved Intravenous Vasopressin Injection. There are no aspects of Par's conduct that are beneficial to

competition. Fresenius Kabi's injury is an integral aspect of Par's unlawful conduct; flows from that which renders Par's conduct unlawful; and its injury is of the type the antitrust laws were intended to prevent.

130. Fresenius Kabi possesses the background and experience to re-enter the Intravenous Vasopressin Injection market. Fresenius Kabi (or one of its predecessor companies) manufactured and sold an Intravenous Vasopressin Injection at least as early as October 1999 and continued to do so until it was forced to stop in March 2015. Fresenius Kabi's ability to manufacture and sell its version of Intravenous Vasopressin Injection for over sixteen years indicates its familiarity with the testing procedures and requirements necessary to manufacture an Intravenous Vasopressin Injection for FDA-approval. In addition, Fresenius Kabi was engaged in its own development program to file an NDA to obtain FDA-approval for Intravenous Vasopressin Injection as early as 2008.

131. Fresenius Kabi has taken and continues to take affirmative action to re-enter the market for Intravenous Vasopressin Injection. Soon after Par received FDA approval for Vasostrict, Fresenius Kabi altered its own NDA development program to file an ANDA with the FDA to obtain approval to sell Intravenous Vasopressin Injection in the United States.

132. Fresenius Kabi approached BCN to supply it Vasopressin API and support its ANDA. Fresenius Kabi had manufactured and sold its Intravenous Vasopressin Injection containing BCN's Vasopressin API since July 2012. Such familiarity with BCN and its Vasopressin API would shorten the amount of time needed for Fresenius Kabi to file its ANDA. Initially, BCN pledged to support Fresenius Kabi's ANDA and provided Fresenius Kabi with samples of Vasopressin API for testing.

133. Fresenius Kabi, however, never received an LOA from BCN because Par and BCN entered into an unduly restrictive exclusive dealing agreement. Upon information and belief, Par required exclusivity from BCN to interfere with Fresenius Kabi's ability to re-enter the market for Intravenous Vasopressin Injection.

134. Fresenius Kabi also approached Bachem to supply it Vasopressin API and support its ANDA. Fresenius Kabi and Bachem have a current business relationship for other products and Bachem has provided Fresenius Kabi with samples of Vasopressin API in the past. Bachem, however, cannot support Fresenius Kabi because of an exclusive contract that prohibited Bachem from shipping Vasopressin API to any other customer. According to Bachem, the exclusive contract is based on current market dynamics. Because Par is the only entity selling Intravenous Vasopressin Injection, upon information and belief, the exclusive agreement for Bachem's Vasopressin API is likely with Par.

135. Fresenius Kabi also contacted PolyPeptide Labs to ask whether PolyPeptide Labs would support Fresenius Kabi's ANDA for Intravenous Vasopressin Injection. PolyPeptide Labs responded that it could not support Fresenius Kabi in the United States because of an exclusive contract.

136. Fresenius Kabi has expended significant resources as part of its plan to obtain FDA approval to market Intravenous Vasopressin Injection. It also has foregone opportunities to develop other generic pharmaceuticals as a result of this dedication of resources, personnel and time to the development of Intravenous Vasopressin Injection.

137. As alleged above, Intravenous Vasopressin Injection is an old drug that was sold in the United States without approval from the FDA. During this period, several manufacturers competed in the Intravenous Vasopressin Injection market. Fresenius Kabi's familiarity with

Intravenous Vasopressin Injection, as well as the historical use of Intravenous Vasopressin Injection would favor FDA-approval of an ANDA.

138. Fresenius Kabi has and continues to be foreclosed from entering the relevant market due to Par's monopolistic ability to lock-up the Vasopressin API necessary for Fresenius Kabi to file an ANDA and compete with Par. As a result, Par continues to maintain a monopoly in the relevant market.

139. As a direct and proximate result of Par's unlawful exclusionary conduct alleged above, Fresenius Kabi is not able to purchase Vasopressin API and, as a result, cannot file an ANDA. Fresenius Kabi is wholly foreclosed from the market for Intravenous Vasopressin Injection.

140. Fresenius Kabi's injury – exclusion from the relevant market – is inseparable from the alleged harm to competition.

141. Fresenius Kabi's re-entry into the relevant market would have broken Par's monopoly. The result would have been unambiguously procompetitive. Fresenius Kabi's re-entry into the market and its introduction of its Intravenous Vasopressin Injection as an alternative to Vasostrict would have benefitted all participants in the market – other than Par.

142. Because Par has prevented Fresenius Kabi and other competitors from entering the Intravenous Vasopressin Injection market, consumers and payors are paying significantly higher prices for Intravenous Vasopressin Injection than they otherwise would pay in a competitive market. Par's unlawful conduct will continue unless injunctive and equitable relief is granted.

D. Par's Exclusionary Conduct Lacks a Valid Procompetitive Business Justification

143. There is no valid procompetitive business justification for Par's exclusionary conduct.

144. The exclusive agreement was not reasonably necessary to protect Par's supply of Vasopressin API. Because BCN would have been free to supply the same Vasopressin API for use in Intravenous Vasopressin Injections sold outside of the United States, any Par restriction prohibiting BCN from supplying Vasopressin API to Fresenius Kabi cannot be justified on the purported basis that an exclusive agreement was necessary to ensure a reliable supply of Vasopressin API.

145. Even if Par had legitimate concerns about the supply of Vasopressin API, like other drug manufacturers, Par could have entered into a less restrictive requirements contract that allowed Vasopressin API suppliers to provide an LOA. Such a contract would have assured Par a source of supply, but not denied Par's competitors access to the same source.

COUNT I
(MONOPOLIZATION – SHERMAN ACT SECTION 2)

146. Fresenius Kabi incorporates its allegations in paragraphs 1–145 as if fully stated herein.

147. Par is the only company with FDA approval to sell Intravenous Vasopressin Injection for use in the United States, and therefore has 100% share of the relevant market. When competitors exited the relevant market, Par's prices increased exponentially. Accordingly, Par possesses market power in the market for the sale of Intravenous Vasopressin Injection in the United States.

148. Par has willfully maintained and abused its market power in the relevant market by engaging in anticompetitive conduct to substantially foreclose the supply of Vasopressin API

to its competitors, thereby restraining trade and competition in the market for Intravenous Vasopressin Injection and enabling Par to raise prices significantly.

149. Par's anticompetitive conduct constitutes an act by which Par willfully exploits and maintains its market power in the relevant market.

150. There is no valid procompetitive business justification for Par's anticompetitive conduct, and any purported legitimate business justifications are mere pretexts.

151. As a direct, substantial, proximate and immediate result of Par's anticompetitive and unlawful actions, Fresenius Kabi has been injured in its business, property, trade, reputation and competitive position in an amount to be established at trial.

152. Par's conduct violates Section 2 of the Sherman Act, 15 U.S.C. § 2.

COUNT II
(ATTEMPTED MONOPOLIZATION – SHERMAN ACT SECTION 2)

153. Fresenius Kabi incorporates its allegations in paragraphs 1–152 as if fully stated herein.

154. Par specifically intended to monopolize the market for the sale of Intravenous Vasopressin Injection in the United States.

155. Par's anticompetitive conduct to foreclose the supply of Vasopressin API to its competitors, thereby restraining trade and competition in the market for Intravenous Vasopressin Injection and enabling Par to raise prices significantly, constitutes an improper attempt to use its significant current market power in the relevant market for the specific purpose of monopolizing that market.

156. In furtherance of this attempt, Par has engaged in anticompetitive conduct, as alleged herein, to bar Fresenius Kabi's access to Vasopressin API and therefore prevent its entry into the relevant market.

157. As a result of Par's conduct, the prices for Intravenous Vasopressin Injection have been, and likely will continue to be, maintained at an artificially high level.

158. If not enjoined, Par will continue to engage in anticompetitive conduct that will further injure Fresenius Kabi and other competitors seeking to enter the relevant market.

159. Par has market power by virtue of its significant share of the market for Intravenous Vasopressin Injection and its ability to maintain supracompetitive prices without consequence. Should Par be successful in maintaining its desired anticompetitive conduct, there is a dangerous probability it will succeed in achieving monopoly power in the relevant market.

160. As a direct, substantial, proximate and immediate result of Par's attempt to monopolize the market, Fresenius Kabi has been injured in its business, property, trade, reputation and competitive position in an amount to be established at trial. Should Par be successful in improperly gaining a monopoly, Fresenius Kabi will further be injured as a result of Par's anticompetitive conduct.

161. Par's conduct violates Section 2 of the Sherman Act, 15 U.S.C. § 2.

COUNT III
(CONSPIRACY TO MONOPOLIZE – SHERMAN ACT SECTION 2)

162. Fresenius Kabi incorporates its allegations in paragraphs 1–161 as if fully stated herein.

163. Par and one or more co-conspirator as alleged herein have acted pursuant to a conspiracy, combination or agreement for the specific purpose of monopolizing the Intravenous Vasopressin Injection market.

164. Par acted with a specific intent to monopolize, and to destroy competition in, the market for Intravenous Vasopressin Injection. Par devised and implemented a calculated campaign to raise the price and profitability of Intravenous Vasopressin Injection by locking up

the supply of Vasopressin API, the most essential ingredient for making Intravenous Vasopressin Injection.

165. Par and at least one co-conspirator acted with the specific intent that Par obtain monopoly power in the relevant market, and through their profit sharing arrangement and the resulting higher prices, Par and at least one co-conspirator have profited significantly from the conspiracy to the detriment of consumers and payors.

166. In furtherance of this conspiracy, Par and at least one co-conspirator have entered into an anticompetitive agreement to supply Vasopressin API exclusively to Par. This conduct has the purpose and effect of denying Par's competitors in the relevant market the supply of an essential raw material.

167. Par's and at least one co-conspirator's conspiracy to monopolize the relevant market had the effect of harming the competitive process. By entering into the exclusive agreement, the conspirators prevented Fresenius Kabi, and other competitors, from obtaining Vasopressin API, enabling Par to significantly raise prices of Intravenous Vasopressin Injection.

168. As a direct, substantial, proximate and immediate result of Par's and at least one co-conspirator's anticompetitive and unlawful actions, Fresenius Kabi has been injured in its business, property, trade, reputation and competitive position in an amount to be established at trial.

169. The conspirators' conduct violates Section 2 of the Sherman Act, 15 U.S.C. § 2.

COUNT IV
(EXCLUSIVE DEALING – SHERMAN ACT SECTION 1)

170. Fresenius Kabi incorporates its allegations in paragraphs 1–169 as if fully stated herein.

171. Par possesses market power in the market for the sale of Intravenous Vasopressin Injection in the United States.

172. Par has entered into anticompetitive exclusive dealing that prohibits Fresenius Kabi and other competitors from accessing Vasopressin API.

173. The purpose and effect of Par's anticompetitive conduct is to substantially foreclose the supply of Vasopressin API to Par's competitors, thereby restraining trade and competition in the market for Intravenous Vasopressin Injection and enabling Par to raise prices significantly.

174. Par's exclusionary conduct substantially forecloses the input necessary for Fresenius Kabi to file an ANDA and enter the relevant market to begin operations and compete with Par.

175. Par's exclusionary conduct has an adverse effect on competition by, among other things, (1) raising entry barriers that prevent new entrants; (2) reducing consumer choice; (3) increasing costs; and (4) increasing prices.

176. As a direct, substantial, proximate and immediate result of Par's anticompetitive and unlawful actions, Fresenius Kabi has been injured in its business, property, trade, reputation and competitive position in an amount to be established at trial.

177. Par's conduct violates Section 1 of the Sherman Act, 15 U.S.C. § 1.

COUNT V
(UNLAWFUL GROUP BOYCOTT – SHERMAN ACT SECTION 1)

178. Fresenius Kabi incorporates its allegations in paragraphs 1–177 as if fully stated herein.

179. Upon information and belief, Par and its co-conspirators agreed to and entered into exclusive contracts for the sale of Vasopressin API to block or, at least, substantially delay

the entry of competitors into the market for Intravenous Vasopressin Injection. Specifically, Par and its co-conspirators knew that these agreements would have the anticompetitive effect of foreclosing Fresenius Kabi and other drug manufacturers from entering or re-entering the relevant market.

180. Upon information and belief, the agreements were induced by anticompetitive payments designed to ensure that Par would avoid having to compete with potential entrants.

181. Through these anticompetitive agreements, Par precluded its competitors, in particular Fresenius Kabi, from accessing Vasopressin API, even solely for the purpose of filing an ANDA, and avoided and foreclosed competition in the relevant market.

182. The purpose and effect of the agreements between and among Par and its co-conspirators was to diminish, eliminate and exclude competition, in particular the competitive threat presented by Fresenius Kabi.

183. Par's conduct constitutes an unlawful contract, combination, concerted action or conspiracy to exclude competition and unreasonably restrain interstate and export commerce in violation of Section 1 of the Sherman Act. Par's conduct did not constitute competition on the merits.

184. There are no legitimate business or pro-competitive justifications for Par's and its co-conspirators' conduct, and any purported legitimate business justifications are mere pretexts.

185. Through its unlawful contract, combination, concerted action and conspiracy, Par has unlawfully injured competition by, among other things alleged in this complaint, raising prices, raising and maintaining barriers to entry, and reducing consumer choice.

186. As a direct, substantial, proximate and immediate result of Par's anticompetitive and unlawful actions, Fresenius Kabi has been injured in its business, property, trade, reputation and competitive position in an amount to be established at trial.

187. Par's and its co-conspirators' conduct violates Section 1 of the Sherman Act, 15 U.S.C. § 1.

COUNT VI
(MONOPOLIZATION – NEW JERSEY ANTITRUST ACT)

188. Fresenius Kabi incorporates its allegations in paragraphs 1–187 as if fully stated herein.

189. Par is the only company with FDA approval to sell Intravenous Vasopressin Injection for use in the United States, and therefore has 100% share of the relevant market. When competitors exited the relevant market, Par's prices increased exponentially. Accordingly, Par possesses market power in the market for the sale of Vasopressin in the United States.

190. Par has willfully maintained and abused its market power in the relevant market through its anti-competitive exclusionary conduct.

191. Par's anticompetitive conduct constitutes an act by which Par willfully exploits and maintains its market power in the relevant market.

192. There is no valid procompetitive business justification for Par's exclusionary conduct, and any purported legitimate business justifications are mere pretexts.

193. As a direct, substantial, proximate and immediate result of Par's anticompetitive and unlawful actions, Fresenius Kabi has been injured in its business, property, trade, reputation and competitive position in an amount to be established at trial.

194. Par's conduct violates the New Jersey Antitrust Act, N.J. Stat. Ann. § 56:9-1 *et seq*.

COUNT VII
(ATTEMPTED MONOPOLIZATION – NEW JERSEY ANTITRUST ACT)

195. Fresenius Kabi incorporates its allegations in paragraphs 1–194 as if fully stated herein.

196. Par specifically intended to monopolize the market for the sale of Intravenous Vasopressin Injection in the United States.

197. Par's anticompetitive conduct to foreclose the supply of Vasopressin API to its competitors, thereby restraining trade and competition in the market for Intravenous Vasopressin Injection and enabling Par to raise prices significantly, constitutes an improper attempt to use its significant market power in the relevant market for the specific purpose of monopolizing that market.

198. In furtherance of this attempt, Par has engaged in specific anticompetitive conduct, as alleged herein, to bar Fresenius Kabi's access to Vasopressin API and therefore prevent its entry into the relevant product market.

199. As a result of Par's conduct, the prices for Intravenous Vasopressin Injection have been, and likely will continue to be, maintained at an artificially high level.

200. If not enjoined, Par will continue to engage in anticompetitive conduct that will further injure Fresenius Kabi and other competitors seeking to enter the relevant market.

201. Par has market power by virtue of its significant share of the market for Intravenous Vasopressin Injection and its ability to maintain supracompetitive prices without consequence. Should Par be successful in maintaining its desired anticompetitive conduct, there is a dangerous probability it will succeed in achieving monopoly power in the relevant market.

202. As a result of Par's attempt to monopolize the market, Fresenius Kabi has been injured in its business, property, trade, reputation and competitive position in an amount to be

established at trial. Should Par be successful in improperly gaining a monopoly, Fresenius Kabi will further be injured as a result of Par's anticompetitive conduct.

203. Par's conduct violates the New Jersey Antitrust Act, N.J. Stat. Ann. § 56:9-1 *et seq*.

COUNT VIII
(CONSPIRACY TO MONOPOLIZE – NEW JERSEY ANTITRUST ACT)

204. Fresenius Kabi incorporates its allegations in paragraphs 1–203 as if fully stated herein.

205. Par and one or more co-conspirators have acted pursuant to a conspiracy, combination or agreement for the specific purpose of monopolizing the Intravenous Vasopressin Injection market.

206. Par acted with a specific intent to monopolize, and to destroy competition in, the market for Intravenous Vasopressin Injection. Par devised and implemented a calculated campaign to raise the price and profitability of Intravenous Vasopressin Injection by locking up the supply of Vasopressin API, the most essential ingredient for making Intravenous Vasopressin Injection.

207. Par and at least one co-conspirator acted with the specific intent that Par obtain monopoly power in the relevant market, and through their profit sharing arrangement and the resulting higher prices, Par and at least one co-conspirator have profited significantly from the conspiracy to the detriment of consumers.

208. In furtherance of this conspiracy, Par and at least one co-conspirator have entered into an anticompetitive agreement to supply Vasopressin API exclusively to Par. This conduct has the purpose and effect of denying Par's competitors in the relevant market the supply of an essential raw material.

209. Par's and at least one co-conspirator's conspiracy to monopolize the relevant market had the effect of harming the competitive process. By entering into the exclusive agreement, the conspirators prevented Fresenius Kabi, and other competitors, from obtaining vasopressin API, enabling Par to significantly raise prices of Intravenous Vasopressin Injection.

210. As a direct, substantial, proximate and immediate result of Par's and at least one co-conspirator's anticompetitive and unlawful actions, Fresenius Kabi has been injured in its business, property, trade, reputation and competitive position in an amount to be established at trial.

211. Par's conduct violates the New Jersey Antitrust Act, N.J. Stat. Ann. § 56:9-1 *et seq*.

COUNT IX
(EXCLUSIVE DEALING – NEW JERSEY ANTITRUST ACT)

212. Fresenius Kabi incorporates its allegations in paragraphs 1–211 as if fully stated herein.

213. Par possesses market power in the market for the sale of Intravenous Vasopressin Injection in the United States.

214. Par has entered into anticompetitive exclusive dealing that prohibits Fresenius Kabi and other competitors from accessing Vasopressin API.

215. The purpose and effect of Par's anticompetitive conduct is to substantially foreclose the supply of Vasopressin API to Par's competitors, thereby restraining trade and competition in the market for Intravenous Vasopressin Injection and enabling Par to raise prices significantly.

216. Par's exclusionary conduct wholly forecloses substantially all of the input necessary for Fresenius Kabi to file an ANDA and enter the relevant market to begin operations and compete with Par.

217. Par's exclusionary conduct has an adverse effect on competition by, among other things, (1) raising entry barriers that prevent new entrants; (2) reducing consumer choice; (3) increasing costs; and (4) increasing prices.

218. As a direct, substantial, proximate and immediate result of Par's anticompetitive and unlawful actions, Fresenius Kabi has been injured in its business, property, trade, reputation and competitive position in an amount to be established at trial.

219. Par's conduct violates the New Jersey Antitrust Act, N.J. Stat. Ann. § 56:9-1 *et seq*.

COUNT X
(UNLAWFUL GROUP BOYCOTT – NEW JERSEY ANTITRUST ACT)

220. Fresenius Kabi incorporates its allegations in paragraphs 1–219 as if fully stated herein.

221. Par and its co-conspirators agreed to and entered into exclusive contracts for the sale of Vasopressin API to block or, at least, substantially delay the entry of competitors into the market for Intravenous Vasopressin Injection. Specifically, Par and its co-conspirators knew that these agreements would have the anticompetitive effect of foreclosing Fresenius Kabi and other drug manufacturers from entering or re-entering the relevant market.

222. Upon information and belief, the agreements were induced by anticompetitive payments designed to ensure that Par would avoid having to compete with potential entrants.

223. Through these anticompetitive agreements, Par precluded its competitors, in particular Fresenius Kabi, from accessing Vasopressin API, even solely for the purpose of filing an ANDA, and avoided and foreclosed competition in the relevant market.

224. The purpose and effect of the agreements between and among Par and its co-conspirators was to diminish, eliminate and exclude competition, in particular the competitive threat presented by Fresenius Kabi.

225. Par's conduct constitutes an unlawful contract, combination, concerted action or conspiracy to exclude competition and unreasonably restrain commerce in violation of the New Jersey Antirust Act. Par's conduct did not constitute competition on the merits.

226. There are no legitimate business or pro-competitive justifications for Par's and its co-conspirators' conduct, and any purported legitimate business justifications are mere pretexts.

227. Through its unlawful contract, combination, concerted action and conspiracy, Par has unlawfully injured competition by, among other things alleged in this complaint, raising prices, raising and maintaining barriers to entry, and reducing consumer choice.

228. As a direct, substantial, proximate and immediate result of Par's anticompetitive and unlawful actions, Fresenius Kabi has been injured in its business, property, trade, reputation and competitive position in an amount to be established at trial.

229. Par's conduct violates the New Jersey Antitrust Act, N.J. Stat. Ann. § 56:9-1 *et seq*.

COUNT XI
(TORTIOUS INTERFERENCE WITH PROSPECTIVE ECONOMIC ADVANTAGE)

230. Fresenius Kabi incorporates its allegations in paragraphs 1–229 as if fully stated herein.

231. Fresenius Kabi had a reasonable expectation of entering into a valid business relationship with BCN to supply Vasopressin API and support its ANDA filing for Intravenous Vasopressin Injection, leading to Fresenius Kabi's re-entry into the Intravenous Vasopressin Injection market.

232. Upon information and belief, Par knew of Fresenius Kabi's reasonable expectancy.

233. Par, in the many ways described herein, intentionally and unjustifiably interfered to cause a termination of Fresenius Kabi's reasonable and legitimate expectancy from being fulfilled.

234. Par acted wrongfully, with the intent to harm Fresenius Kabi.

235. Par's tortious conduct harmed Fresenius Kabi in several ways described herein.

236. Given the past supplier relationship between Fresenius Kabi and BCN for Vasopressin API, and BCN's initial support for Fresenius Kabi's ANDA application before Par's bad faith actions, Fresenius Kabi had a reasonable probability of receiving the anticipated economic benefit.

237. Fresenius Kabi has been injured and suffered damages as a result of Par's interference, including, but not limited to, lost profits resulting from Fresenius Kabi's delayed re-entry into the Intravenous Vasopressin Injection market.

JURY DEMAND

238. Plaintiff demands trial by jury on all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, Fresenius Kabi requests that the Court enter judgment in its favor and against Defendants for:

a. Actual damages in an amount to be determined at trial;

b. Treble damages;

c. Reasonable attorneys' fees and costs;

d. Punitive damages;

e. A permanent injunction against Par from any further conduct calculated to prevent Fresenius Kabi from contracting with BCN; and

f. Such other relief as the Court deems just and proper.

Dated: July 27, 2016
New York, New York

Respectfully submitted,

McGUIREWOODS, LLP

By: /s/ William E. Goydan

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2

I hereby certify that the within matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding. I certify under penalty of perjury that the foregoing is true and correct.

Dated: July 27, 2016
New York, New York

By: /s/ William E. Goydan
William E. Goydan
(NJ Bar # 036041988)

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1

I hereby certify that the above-captioned matter is not subject to compulsory arbitration because Plaintiff seeks damages in excess of $150,000 exclusive of interests and costs, and any claim for punitive damages, and also seeks injunctive relief.

Dated: July 27, 2016
New York, New York

By: /s/ William E. Goydan
William E. Goydan
(NJ Bar # 036041988)

CERTIFICATE OF SERVICE

I hereby certify that on July 27, 2016, I electronically filed the foregoing COMPLAINT with the Clerk of the Court using the CM/ECF system, which will send notification and service of such filing to all registered counsel of record.

By: /s/ William E. Goydan
William E. Goydan
(NJ Bar # 036041988)